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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,633	04/20/2001	Gregory A. Demopoulos	OMER117356	2163

26389 7590 09/05/2003

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EXAMINER

O HARA, EILEEN B

ART UNIT PAPER NUMBER

1646

DATE MAILED: 09/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/839,633	<b>Applicant(s)</b> DEMOPULOS ET AL.	
	<b>Examiner</b> Eileen O'Hara	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 20-50 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other:  |

### **DETAILED ACTION**

1. Claims 20-50 are pending in the instant application. Claims 1-19 have been canceled and as requested by Applicant in the preliminary amendment filed Feb. 15, 2002.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 20-22, 25-41 and 44-50 in part, drawn to a method of preemptively inhibiting pain and inflammation at a wound during a surgical procedure comprising delivering to the wound sTNFR with or without an additional pain/inflammation inhibitory agent selected to act on a different molecular target, classified in class 514, subclass 12.

II. Claims 20-22, 25-41 and 44-50 in part, drawn to a method of preemptively inhibiting pain and inflammation at a wound during a surgical procedure comprising delivering to the wound chimeric rhTNFR:Fc with or without an additional pain/inflammation inhibitory agent selected to act on a different molecular target, classified in class 514, subclass 12.

III. Claims 20-22, 25-41 and 44-50 in part, drawn to a method of preemptively inhibiting pain and inflammation at a wound during a surgical procedure comprising delivering to the wound human type I IL-1R with or without an additional pain/inflammation inhibitory agent selected to act on a different molecular target, classified in class 514, subclass 12.

IV. Claims 20-22, 25-41 and 44-50 in part, drawn to a method of preemptively inhibiting pain and inflammation at a wound during a surgical procedure comprising delivering to the wound human type I IL-1R fusion protein with DYKDDDDK on N-terminus with or

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without an additional pain/inflammation inhibitory agent selected to act on a different molecular target, classified in class 514, subclass 12.

V. Claims 20, 23-39 and 42-50 in part, drawn to a method of preemptively inhibiting pain and inflammation at a wound during a surgical procedure comprising delivering to the wound sIL-6R with or without an additional pain/inflammation inhibitory agent selected to act on a different molecular target, classified in class 514, subclass 12.

VI. Claims 20-22, 25-41 and 44-50 in part, drawn to a method of preemptively inhibiting pain and inflammation at a wound during a surgical procedure comprising delivering to the wound bFGF receptor with or without an additional pain/inflammation inhibitory agent selected to act on a different molecular target, classified in class 514, subclass 12.

VII. Claims 20-22, 25-41 and 44-50 in part, drawn to a method of preemptively inhibiting pain and inflammation at a wound during a surgical procedure comprising delivering to the wound PDGF with or without an additional pain/inflammation inhibitory agent selected to act on a different molecular target, classified in class 514, subclass 12.

VIII. Claims 20-22, 25-41 and 44-50 in part, drawn to a method of preemptively inhibiting pain and inflammation at a wound during a surgical procedure comprising delivering to the wound sFGFR with or without an additional pain/inflammation inhibitory agent selected to act on a different molecular target, classified in class 514, subclass 12.

IX. Claims 20-50 in part, drawn to a method of preemptively inhibiting pain and inflammation at a wound during a surgical procedure comprising delivering to the wound a specific combination of soluble receptor with or without an additional pain/inflammation

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inhibitory agent selected to act on a different molecular target, classified in class 514, subclass 12.

The inventions are distinct, each from the other because of the following reasons:

The inventions require treatments with patentably distinct compounds, each of which can be administered without the others, and each would require a separate search, and are therefore patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their separate search requirements and/or divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: treatment with additional pain/inflammatory agent selected to act on a different molecular target than the soluble receptor, selected from the agents listed in 37.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Dennis K. Shelton on Sept. 3, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

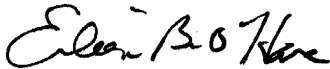
Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

A handwritten signature in black ink, appearing to read "Eileen B. O'Hara". The signature is written in a cursive, flowing style.

Patent Examiner